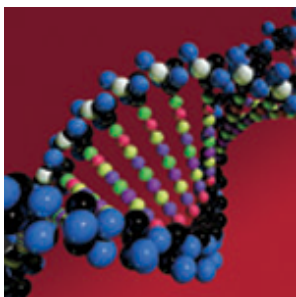


# Response to Request from the NIH for Public Comment on the Proposed NTP Review Process for the Report on Carcinogens



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On Behalf of Momentive Specialty Chemicals, Inc

ENVIRON



# Nomination and Selection of Candidate Substances

- Draft Revised RoC Process requires Office of Report on Carcinogens (ORoC) to determine if there is sufficient information to justify evaluation and consideration
- Definitions and justification not provided in proposed review



# Scientific Evaluation of Candidate Substances

- Methodology for identifying, critically reviewing and synthesizing study results must be transparent and fully described
- Lacks standard approach
- Invites subjective decision-making and unpredictable use of methods from substance to substance



# Causal Determinations

- Requires all relevant published epidemiological studies addressing specific exposure-disease relationships be identified and critically evaluated
- Important scientific step in determining causation
- Draft revised RoC process does not identify how the relevant studies will be identified or the criteria for evaluation



# Weight of Evidence

- Studies with reasonable minimal quality standards should be synthesized, weighting studies of greater quality more than those with one or more serious weaknesses
- Negative, equivocal and positive results all should be carefully considered



# Peer Review

- Important role in evaluating and enhancing the scientific quality of a scientific work
- Value of review enhanced when:
  - peers are independent of the study or review being peer-reviewed
  - reviewers' comments are objective
  - peer-review comments are considered by the investigators and individually addressed (whether adopted or not).



# Public Comment

- Unclear how will be considered
- May be (often is) provided by individuals or organizations expert in the subject matter of the study or review, as well as lay persons
- Comments from qualified scientists and other experts provide a valuable service to the government and to society, and should be respected and considered as if they were provided by a peer reviewer or scientific advisor.